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8 BAYER HEALTHCARE PHARMACEUTICALS INC.

9 UNITED STATES DISTRICT COURT
10 NORTHERN DISTRICT OF CALIFORNIA
11 SAN FRANCISCO DIVISION

12 JOE V. SANCHEZ and SANDRA L.
13 ROARTY-SANCHEZ,,
14

15 Plaintiffs,

16 v.

17 BAYER HEALTHCARE
18 PHARMACEUTICALS, INC.; BAYER
19 HEALTHCARE LLC; GENERAL
20 ELECTRIC COMPANY; GE
21 HEALTHCARE, INC.; TYCO
22 INTERNATIONAL, INC.; COVIDIEN,
23 INC.; TYCO HEALTHCARE GROUP, LP;
24 MALLINCKRODT, INC.; and BRACCO
25 DIAGNOSTICS, INC.,
26

27 Defendants.
28

Case No. CV-08-0973 (EMC)

**ANSWER OF DEFENDANT BAYER
HEALTHCARE PHARMACEUTICALS
INC.**

**(Pending Transfer to: In re: Gadolinium
Contrast Dyes Products Liability
Litigation, MDL No. 1909, N.D. Ohio)**

[JURY TRIAL DEMANDED]

22 Defendant Bayer Healthcare Pharmaceuticals Inc. (hereinafter "BHCP") responds to
23 Plaintiffs' Complaint as follows:

24 1. BHCP is without knowledge or information sufficient to form a belief as to
25 the truth of the allegations in the first sentence in paragraph 1 and the allegation that
26 Plaintiff has impaired kidney function. BHCP admits, on information and belief, that the
27 symptoms of nephrogenic systemic fibrosis ("NSF"), formerly known as nephrogenic
28 fibrosing dermopathy, may include pain, that NSF may be fatal, and that currently, there

1 is no known cure for NSF, although various treatments have been employed with variable
2 successes. BHCP admits that it marketed Magnevist® in the United States as safe for use
3 with magnetic resonance imaging (“MRI”) when administered to patients by physicians
4 in accordance with the labeling and prescribing information approved by the United
5 States Food and Drug Administration (the “FDA”). BHCP denies that it failed to provide
6 appropriate warnings regarding Magnevist® and denies the remaining allegations in
7 paragraph 1 to the extent that they relate to BHCP and/or to Magnevist®. The remaining
8 allegations in paragraph 1 are directed to other defendants and therefore no response is
9 required by BHCP. To the extent that a response is required, on information and belief,
10 BHCP denies that at any relevant time Bayer HealthCare LLC (“BHC”) manufactured,
11 marketed or sold any gadolinium-based contrast agents. BHCP is without knowledge or
12 information sufficient to form a belief as to the truth of the remaining allegations in
13 paragraph 1.

14 2. The allegations in paragraph 2 state conclusions of law to which no
15 response is required by BHCP. To the extent that a response is required, BHCP is
16 without knowledge or information sufficient to form a belief as to the truth of the
17 allegations in paragraph 2, except that BHCP denies that Plaintiffs are entitled to any
18 relief from BHCP.

19 3. BHCP is without knowledge or information sufficient to form a belief as to
20 the truth of the allegations in paragraph 3, except that BHCP denies that Plaintiffs are
21 entitled to any relief from BHCP.

22 4. BHCP is without knowledge or information sufficient to form a belief as to
23 the truth of the allegations in paragraph 4.

24 5. BHCP admits that it markets and sells the gadolinium-based contrast agent
25 Magnevist® in the United States. BHCP denies that it manufactures Magnevist®. On
26 information and belief, BHCP denies that at any relevant time BHC manufactured,
27 marketed or sold Magnevist®. BHCP is without knowledge or information sufficient to
28 form a belief as to the truth of the remaining allegations in paragraph 5. For a further

1 response, to the extent that the Complaint contains allegations directed to BHC by the use
2 of the terms “Bayer” or “Defendants” or otherwise, BHCP responds on behalf of itself
3 only and makes no response on behalf of BHC.

4 6. BHCP admits that BHC is a limited liability company formed in Delaware
5 and that its principal place of business is located in New York. BHCP denies any
6 remaining allegations in paragraph 6.

7 7. BHCP admits that it is a Delaware corporation with its principal place of
8 business in New Jersey. BHCP denies the remaining allegations in paragraph 7.

9 8. BHCP admits that at various times it distributed, sold, marketed and
10 promoted Magnevist® in the United States. BHCP denies that it designed or
11 manufactured Magnevist®. On information and belief, BHPC denies that at any relevant
12 time BHC designed, manufactured, distributed, sold, marketed or promoted Magnevist®.
13 Because of the vagueness and ambiguity of the remaining allegations in paragraph 8,
14 BHCP is without knowledge or information sufficient to form a belief as to the truth of
15 those allegations.

16 9. The allegations in paragraph 9 are directed to other defendants, and
17 therefore no response is required by BHCP. To the extent that a response is required,
18 BHCP is without knowledge or information sufficient to form a belief as to the truth of
19 the allegations in paragraph 9.

20 10. The allegations in paragraph 10 are directed to another defendant, and
21 therefore no response is required by BHCP. To the extent that a response is required,
22 BHCP admits, on information and belief, that General Electric Company is a corporation
23 incorporated under the laws of the State of New York with its principal place of business
24 in Connecticut. BHCP is without knowledge or information sufficient to form a belief as
25 to the truth of the remaining allegations in paragraph 10.

26 11. The allegations in paragraph 11 are directed to another defendant, and
27 therefore no response is required by BHCP. To the extent that a response is required,
28 BHCP admits, on information and belief, that GE Healthcare Inc. is a corporation

1 incorporated under the laws of the State of Delaware with its principal place of business
2 in New Jersey. BHCP is without knowledge or information sufficient to form a belief as
3 to the truth of the remaining allegations in paragraph 11.

4 12. The allegations in paragraph 12 are directed to other defendants, and
5 therefore no response is required by BHCP. To the extent that a response is required,
6 BHCP is without knowledge or information sufficient to form a belief as to the truth of
7 the allegations in paragraph 12.

8 13. The allegations in paragraph 13 are directed to other defendants, and
9 therefore no response is required by BHCP. To the extent that a response is required,
10 BHCP is without knowledge or information sufficient to form a belief as to the truth of
11 the allegations in paragraph 13.

12 14. The allegations in paragraph 14 are directed to another defendant, and
13 therefore no response is required by BHCP. To the extent that a response is required,
14 BHCP is without knowledge or information sufficient to form a belief as to the truth of
15 the allegations in paragraph 14.

16 15. The allegations in paragraph 15 are directed to other defendants, and
17 therefore no response is required by BHCP. To the extent that a response is required,
18 BHCP is without knowledge or information sufficient to form a belief as to the truth of
19 the allegations in paragraph 15.

20 16. The allegations in paragraph 16 are directed to other defendants, and
21 therefore no response is required by BHCP. To the extent that a response is required,
22 BHCP admits, on information and belief, that Mallinckrodt, Inc. is a corporation
23 incorporated under the laws of the State of Delaware with its principal place of business
24 in Missouri. BHCP is without knowledge or information sufficient to form a belief as to
25 the truth of the remaining allegations in paragraph 16.

26 17. The allegations in paragraph 17 are directed to other defendants, and
27 therefore no response is required by BHCP. To the extent that a response is required,
28 BHCP is without knowledge or information sufficient to form a belief as to the truth of

1 the allegations in paragraph 17.

2 18. The allegations in paragraph 18 are directed to another defendant, and
3 therefore no response is required by BHCP. To the extent that a response is required,
4 BHCP is without knowledge or information sufficient to form a belief as to the truth of
5 the allegations in paragraph 18.

6 19. The allegations in paragraph 19 are directed to another defendant, and
7 therefore no response is required by BHCP. To the extent that a response is required,
8 BHCP admits, on information and belief, that Bracco Diagnostics, Inc. is a corporation
9 incorporated under the laws of the State of Delaware with its principal place of business
10 in New Jersey. BHCP is without knowledge or information sufficient to form a belief as
11 to the truth of any remaining allegations in paragraph 19.

12 20. The allegations in paragraph 20 are directed to another defendant, and
13 therefore no response is required by BHCP. To the extent that a response is required,
14 BHCP is without knowledge or information sufficient to form a belief as to the truth of
15 the allegations in paragraph 20.

16 21. BHCP admits that the Complaint refers to certain entities as “Defendants”.
17 BHCP is without knowledge or information sufficient to form a belief as to the truth of
18 any remaining allegations in paragraph 21.

19 22. BHCP is without knowledge or information sufficient to form a belief as to
20 the truth of the allegations in paragraph 22.

21 23. BHCP admits, on information and belief, that NSF is characterized by
22 fibrosis of the skin and may involve fibrosis of other tissues throughout the body, that
23 symptoms of NSF may include discoloration, thickening, tightening and swelling of the
24 skin, that the symptoms of NSF may also include contractures around the joints that may
25 impair mobility, a burning or itching sensation, and pain, and that in some cases, the skin
26 may feel “woody”. BHCP further admits, on information and belief, that there have been
27 reports of NSF involving the lungs, heart, liver and muscles, that the clinical course of
28 NSF can be progressive and may be fatal, and that currently, there is no known cure for

1 NSF, although various treatments have been employed with variable successes. BHCP
2 denies, on information and belief, the remaining or inconsistent allegations in paragraph
3 23.

4 24. Because of the vagueness and ambiguity of the allegations in the first
5 sentence in paragraph 24, BHCP is without knowledge or information sufficient to form a
6 belief as to the truth of those allegations. BHCP denies the remaining allegations in
7 paragraph 24.

8 25. BHCP admits, on information and belief, that gadolinium is a heavy metal
9 and that it is not normally detected in the human body at the threshold levels of detection
10 typically employed. Because of the vagueness and ambiguity of the remaining
11 allegations in the first and second sentences in paragraph 25, BHCP is without knowledge
12 or information sufficient to form a belief as to the truth of those allegations. BHCP
13 denies the remaining allegations in paragraph 25.

14 26. Because of the vagueness and ambiguity of the allegations in paragraph 26,
15 BHCP is without knowledge or information sufficient to form a belief as to the truth of
16 those allegations.

17 27. BHCP admits that Magnevist® is cleared from the body through the
18 kidneys. BHCP denies any allegation that Magnevist® is not safe for use with MRI
19 when administered to patients by physicians in accordance with the labeling and
20 prescribing information approved by the FDA. Because of the vagueness and ambiguity
21 of the remaining allegations in the second and third sentences in paragraph 27, BHCP is
22 without knowledge or information sufficient to form a belief as to the truth of those
23 allegations. BHCP denies the remaining allegations in paragraph 27.

24 28. BHCP denies that it manufactured any gadolinium-based contrast agents,
25 and accordingly, BHCP denies the allegations in paragraph 28 to the extent that they
26 relate to BHCP. The remaining allegations in paragraph 28 are directed to other
27 defendants, and therefore no response is required by BHCP. To the extent that a response
28 is required, BHCP denies, on information and belief, that at any relevant time BHC

1 manufactured any gadolinium-based contrast agents. BHCP is without knowledge or
2 information sufficient to form a belief as to the truth of the remaining allegations in
3 paragraph 28.

4 29. Because of the vagueness and ambiguity of the allegations in paragraph 29,
5 BHCP is without knowledge or information sufficient to form a belief as to the truth of
6 those allegations.

7 30. Because of the vagueness and ambiguity of the allegations in paragraph 30,
8 BHCP is without knowledge or information sufficient to form a belief as to the truth of
9 those allegations. For a further response, BHCP states that prior to 2006, no reported
10 studies suggested a possible association between gadolinium-based contrast agents and
11 NSF.

12 31. BHCP is without knowledge or information sufficient to form a belief as to
13 the truth of the allegations in paragraph 31.

14 32. BHCP is without knowledge or information sufficient to form a belief as to
15 the truth of the allegations in paragraph 32.

16 33. BHCP denies the allegations in paragraph 33 to the extent that they relate to
17 BHCP and/or to Magnevist®. The remaining allegations in paragraph 33 are directed to
18 other defendants, and therefore no response is required by BHCP. To the extent that a
19 response is required, BHCP denies, on information and belief, that at any relevant time
20 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
21 without knowledge or information sufficient to form a belief as to the truth of the
22 remaining allegations in paragraph 33.

23 34. BHCP denies the allegations in paragraph 34 to the extent that they relate to
24 BHCP and/or to Magnevist®. The remaining allegations in paragraph 34 are directed to
25 other defendants, and therefore no response is required by BHCP. To the extent that a
26 response is required, BHCP denies, on information and belief, that at any relevant time
27 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
28 without knowledge or information sufficient to form a belief as to the truth of the

1 remaining allegations in paragraph 34.

2 35. BHCP denies the allegations in paragraph 35 to the extent that they relate to
3 BHCP and/or to Magnevist®. The remaining allegations in paragraph 35 are directed to
4 other defendants, and therefore no response is required by BHCP. To the extent that a
5 response is required, BHCP denies, on information and belief, that at any relevant time
6 BHC manufactured, marketed, distributed or sold any gadolinium-based contrast agents.
7 BHCP is without knowledge or information sufficient to form a belief as to the truth of
8 the remaining allegations in paragraph 35.

9 36. BHCP denies the allegations in paragraph 36 to the extent that they relate to
10 BHCP and/or to Magnevist®. The remaining allegations in paragraph 36 are directed to
11 other defendants, and therefore no response is required by BHCP. To the extent that a
12 response is required, BHCP denies, on information and belief, that at any relevant time
13 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
14 without knowledge or information sufficient to form a belief as to the truth of the
15 remaining allegations in paragraph 36.

16 37. The allegations in paragraph 37 purport to describe a September 2007 letter
17 to healthcare professionals, which is in writing and speaks for itself. To the extent that
18 Plaintiffs' allegations regarding the contents of that letter are inconsistent with the actual
19 language of the letter, BHCP denies those allegations. For a further response, at all
20 relevant times, BHCP provided appropriate warnings regarding the risks associated with
21 the use of Magnevist®, including at various times the provision of information and
22 warnings on BHCP's website. BHCP denies the remaining allegations in paragraph 37 to
23 the extent that they relate to BHCP. The remaining allegations in paragraph 37 are
24 directed to other defendants, and therefore no response is required by BHCP. To the
25 extent that a response is required, BHCP denies, on information and belief, that at any
26 relevant time BHC manufactured, marketed or sold any gadolinium-based contrast
27 agents. BHCP is without knowledge or information sufficient to form a belief as to the
28 truth of the remaining allegations in paragraph 37.

1 38. BHCP denies that it failed to provide appropriate warnings regarding
2 Magnevist® and denies that BHCP had any duty to provide warnings directly to Plaintiff.
3 BHCP denies the remaining allegations in paragraph 38 to the extent that they relate to
4 BHCP and/or to Magnevist®. The remaining allegations in paragraph 38 are directed to
5 other defendants, and therefore no response is required by BHCP. To the extent that a
6 response is required, BHCP denies, on information and belief, that at any relevant time
7 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
8 without knowledge or information sufficient to form a belief as to the truth of the
9 remaining allegations in paragraph 38.

10 39. BHCP denies the allegations in paragraph 39 to the extent that they relate to
11 BHCP and/or to Magnevist®. The remaining allegations in paragraph 39 are directed to
12 other defendants, and therefore no response is required by BHCP. To the extent that a
13 response is required, BHCP denies, on information and belief, that at any relevant time
14 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
15 without knowledge or information sufficient to form a belief as to the truth of the
16 remaining allegations in paragraph 39.

17 40. BHCP denies the allegations in paragraph 40 to the extent that they relate to
18 BHCP and/or to Magnevist®. The remaining allegations in paragraph 40 are directed to
19 other defendants, and therefore no response is required by BHCP. To the extent that a
20 response is required, BHCP denies, on information and belief, that at any relevant time
21 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
22 without knowledge or information sufficient to form a belief as to the truth of the
23 remaining allegations in paragraph 40.

24 41. BHCP denies the allegations in paragraph 41 to the extent that they relate to
25 BHCP and/or to Magnevist®. The remaining allegations in paragraph 41 are directed to
26 other defendants, and therefore no response is required by BHCP. To the extent that a
27 response is required, BHCP denies, on information and belief, that at any relevant time
28 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is

1 without knowledge or information sufficient to form a belief as to the truth of the
2 remaining allegations in paragraph 41.

3 42. The allegations in paragraph 42 state conclusions of law to which no
4 response is required by BHCP. To the extent that a response is required, BHCP denies
5 the allegations in paragraph 42 to the extent that they relate to BHCP and/or to
6 Magnevist®. The remaining allegations in paragraph 42 are directed to other defendants,
7 and therefore no response is required by BHCP. To the extent that a response is required,
8 BHCP denies, on information and belief, that at any relevant time BHC manufactured,
9 marketed or sold any gadolinium-based contrast agents. BHCP is without knowledge or
10 information sufficient to form a belief as to the truth of the remaining allegations in
11 paragraph 42.

12 43. BHCP denies the allegations in paragraph 43 to the extent that they relate to
13 BHCP. The remaining allegations in paragraph 43 are directed to other defendants, and
14 therefore no response is required by BHCP. To the extent that a response is required,
15 BHCP denies, on information and belief, that at any relevant time BHC manufactured,
16 marketed or sold any gadolinium-based contrast agents. BHCP is without knowledge or
17 information sufficient to form a belief as to the truth of the remaining allegations in
18 paragraph 43.

19 **FIRST CAUSE OF ACTION**

20 44. BHCP incorporates by reference its responses to the preceding paragraphs
21 as if fully set forth herein.

22 45. BHCP denies the allegations in paragraph 45 to the extent that they relate to
23 BHCP and/or to Magnevist®. The remaining allegations in paragraph 45 are directed to
24 other defendants, and therefore no response is required by BHCP. To the extent that a
25 response is required, BHCP denies, on information and belief, that at any relevant time
26 BHC manufactured, marketed or sold any gadolinium-based contrast agents or any MRI
27 or MRA machines. BHCP is without knowledge or information sufficient to form a
28 belief as to the truth of the remaining allegations in paragraph 45.

1 46. BHCP denies the allegations in paragraph 46 to the extent that they relate to
2 BHCP and/or to Magnevist®. The remaining allegations in paragraph 46 are directed to
3 other defendants, and therefore no response is required by BHCP. To the extent that a
4 response is required, BHCP denies, on information and belief, that at any relevant time
5 BHC manufactured, designed, sold, supplied or marketed any gadolinium-based contrast
6 agents. BHCP is without knowledge or information sufficient to form a belief as to the
7 truth of the remaining allegations in paragraph 46.

8 **SECOND CAUSE OF ACTION**

9 47. BHCP incorporates by reference its responses to the preceding paragraphs
10 as if fully set forth herein.

11 48. BHCP admits that at various times it distributed, sold and supplied
12 Magnevist® in the United States. BHCP denies the remaining allegations in paragraph
13 48 to the extent that they relate to BHCP. The remaining allegations in paragraph 48 are
14 directed to other defendants, and therefore no response is required by BHCP. To the
15 extent that a response is required, BHCP denies, on information and belief, that at any
16 relevant time BHC manufactured, designed, distributed, sold or supplied any gadolinium-
17 based contrast agents or any MRI or MRA machines. BHCP is without knowledge or
18 information sufficient to form a belief as to the truth of the remaining allegations in
19 paragraph 48.

20 49. BHCP denies the allegations in paragraph 49 to the extent that they relate to
21 BHCP and/or to Magnevist®. The remaining allegations in paragraph 49 are directed to
22 other defendants, and therefore no response is required by BHCP. To the extent that a
23 response is required, BHCP denies, on information and belief, that at any relevant time
24 BHC manufactured or supplied any gadolinium-based contrast agents. BHCP is without
25 knowledge or information sufficient to form a belief as to the truth of the remaining
26 allegations in paragraph 49.

27 50. BHCP denies the allegations in paragraph 50 to the extent that they relate to
28 BHCP and/or to Magnevist®. The remaining allegations in paragraph 50 are directed to

1 other defendants, and therefore no response is required by BHCP. To the extent that a
2 response is required, BHCP denies, on information and belief, that at any relevant time
3 BHC manufactured, marketed or sold any gadolinium-based contrast agents or any MRI
4 or MRA machines. BHCP is without knowledge or information sufficient to form a
5 belief as to the truth of the remaining allegations in paragraph 50.

6 51. BHCP denies the allegations in paragraph 51 to the extent that they relate to
7 BHCP and/or to Magnevist®. The remaining allegations in paragraph 51 are directed to
8 other defendants, and therefore no response is required by BHCP. To the extent that a
9 response is required, BHCP denies, on information and belief, that at any relevant time
10 BHC manufactured, designed, sold, supplied or marketed any gadolinium-based contrast
11 agents. BHCP is without knowledge or information sufficient to form a belief as to the
12 truth of the remaining allegations in paragraph 51.

13 **THIRD CAUSE OF ACTION**

14 52. BHCP incorporates by reference its responses to the preceding paragraphs
15 as if fully set forth herein.

16 53. BHCP admits that it marketed Magnevist® in the United States as safe for
17 use with MRI when administered to patients by physicians in accordance with the
18 labeling and prescribing information approved by the FDA. BHCP denies that it directly
19 marketed Magnevist® to consumers. BHCP denies the remaining allegations in
20 paragraph 53 to the extent that they relate to BHCP. The remaining allegations in
21 paragraph 53 are directed to other defendants, and therefore no response is required by
22 BHCP. To the extent that a response is required, BHCP denies, on information and
23 belief, that at any relevant time BHC manufactured, marketed, sold or tested any
24 gadolinium-based contrast agents. BHCP is without knowledge or information sufficient
25 to form a belief as to the truth of the remaining allegations in paragraph 53.

26 54. BHCP denies that it failed to adequately test or to provide adequate
27 disclosures regarding Magnevist®, and BHCP denies the remaining allegations in
28 paragraph 54 to the extent that they relate to BHCP. The remaining allegations in

1 paragraph 54 are directed to other defendants, and therefore no response is required by
2 BHCP. To the extent that a response is required, BHCP denies, on information and
3 belief, that at any relevant time BHC manufactured, marketed, sold or tested any
4 gadolinium-based contrast agents. BHCP is without knowledge or information sufficient
5 to form a belief as to the truth of the remaining allegations in paragraph 54.

6 55. BHCP denies the allegations in paragraph 55 to the extent that they relate to
7 BHCP and/or to Magnevist®. The remaining allegations in paragraph 55 are directed to
8 other defendants, and therefore no response is required by BHCP. To the extent that a
9 response is required, BHCP denies, on information and belief, that at any relevant time
10 BHC tested, manufactured, designed, sold, supplied or marketed any gadolinium-based
11 contrast agents. BHCP is without knowledge or information sufficient to form a belief as
12 to the truth of the remaining allegations in paragraph 55.

13 **FOURTH CAUSE OF ACTION**

14 56. BHCP incorporates by reference its responses to the preceding paragraphs
15 as if fully set forth herein.

16 57. The allegations in paragraph 57 state conclusions of law to which no
17 response is required by BHCP. To the extent that a response is required, BHCP denies
18 that BHCP breached any applicable duty of care, as alleged in the Complaint, and BHCP
19 denies that Magnevist® posed an unreasonable risk of bodily harm and adverse events.
20 Because of the vagueness and ambiguity of the remaining allegations in paragraph 57 to
21 the extent that they relate to BHCP, BHCP is without knowledge or information
22 sufficient to form a belief as to the truth of those allegations. The remaining allegations
23 in paragraph 57 are directed to other defendants, and therefore no response is required by
24 BHCP. To the extent that a response is required, BHCP denies, on information and
25 belief, that at any relevant time BHC designed, tested, manufactured, labeled, marketed,
26 sold or distributed any gadolinium-based contrast agents or any MRI or MRA machines.
27 BHCP is without knowledge or information sufficient to form a belief as to the truth of
28 the remaining allegations in paragraph 57.

1 58. The allegations in paragraph 58 state conclusions of law to which no
2 response is required by BHCP. To the extent that a response is required, BHCP denies
3 the allegations in paragraph 58 to the extent that they relate to BHCP and/or to
4 Magnevist®. The remaining allegations in paragraph 58 are directed to other defendants,
5 and therefore no response is required by BHCP. To the extent that a response is required,
6 BHCP denies, on information and belief, that at any relevant time BHC designed,
7 manufactured, sold, tested, marketed or distributed any gadolinium-based contrast agents
8 or any MRI or MRA machines. BHCP is without knowledge or information sufficient to
9 form a belief as to the truth of the remaining allegations in paragraph 58.

10 59. The allegations in paragraph 59 state conclusions of law to which no
11 response is required by BHCP. To the extent that a response is required, BHCP denies
12 the allegations in paragraph 59 to the extent that they relate to BHCP and/or to
13 Magnevist®. The remaining allegations in paragraph 59 are directed to other defendants,
14 and therefore no response is required by BHCP. To the extent that a response is required,
15 BHCP denies, on information and belief, that at any relevant time BHC manufactured,
16 marketed, sold or labeled any gadolinium-based contrast agents or any MRI or MRA
17 machines. BHCP is without knowledge or information sufficient to form a belief as to
18 the truth of the remaining allegations in paragraph 59.

19 60. The allegations in paragraph 60 state conclusions of law to which no
20 response is required by BHCP. To the extent that a response is required, BHCP denies
21 the allegations in paragraph 60 to the extent that they relate to BHCP and/or to
22 Magnevist®. The remaining allegations in paragraph 60 are directed to other defendants,
23 and therefore no response is required by BHCP. To the extent that a response is required,
24 BHCP denies, on information and belief, that at any relevant time BHC manufactured or
25 marketed any gadolinium-based contrast agents or any MRI or MRA machines. BHCP is
26 without knowledge or information sufficient to form a belief as to the truth of the
27 remaining allegations in paragraph 60.

28 61. BHCP denies the allegations in paragraph 61 to the extent that they relate to

1 BHCP and/or to Magnevist®. The remaining allegations in paragraph 61 are directed to
2 other defendants, and therefore no response is required by BHCP. To the extent that a
3 response is required, BHCP denies, on information and belief, that at any relevant time
4 BHC manufactured, marketed or sold any gadolinium-based contrast agents or any MRI
5 or MRA machines. BHCP is without knowledge or information sufficient to form a
6 belief as to the truth of the remaining allegations in paragraph 61.

7 62. BHCP denies the allegations in paragraph 62 to the extent that they relate to
8 BHCP and/or to Magnevist®. The remaining allegations in paragraph 62 are directed to
9 other defendants, and therefore no response is required by BHCP. To the extent that a
10 response is required, BHCP denies, on information and belief, that at any relevant time
11 BHC manufactured, marketed or sold any gadolinium-based contrast agents or any MRI
12 or MRA machines. BHCP is without knowledge or information sufficient to form a
13 belief as to the truth of the remaining allegations in paragraph 62.

14 63. BHCP denies the allegations in paragraph 63 to the extent that they relate to
15 BHCP and/or to Magnevist®. The remaining allegations in paragraph 63 are directed to
16 other defendants, and therefore no response is required by BHCP. To the extent that a
17 response is required, BHCP denies, on information and belief, that at any relevant time
18 BHC manufactured, marketed or sold any gadolinium-based contrast agents or any MRI
19 or MRA machines. BHCP is without knowledge or information sufficient to form a
20 belief as to the truth of the remaining allegations in paragraph 63.

21 **FIFTH CAUSE OF ACTION**

22 64. BHCP incorporates by reference its responses to the preceding paragraphs
23 as if fully set forth herein.

24 65. BHCP denies the allegations in paragraph 65 to the extent that they relate to
25 BHCP and/or to Magnevist®. The remaining allegations in paragraph 65 are directed to
26 other defendants, and therefore no response is required by BHCP. To the extent that a
27 response is required, BHCP denies, on information and belief, that at any relevant time
28 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is

1 without knowledge or information sufficient to form a belief as to the truth of the
2 remaining allegations in paragraph 65.

3 66. BHCP admits that it marketed Magnevist® in the United States as safe for
4 use with MRI when administered to patients by physicians in accordance with the
5 labeling and prescribing information approved by the FDA. BHCP denies the remaining
6 allegations in paragraph 66 to the extent that they relate to BHCP. The remaining
7 allegations in paragraph 66 are directed to other defendants, and therefore no response is
8 required by BHCP. To the extent that a response is required, BHCP denies, on
9 information and belief, that at any relevant time BHC manufactured, marketed or sold
10 any gadolinium-based contrast agents. BHCP is without knowledge or information
11 sufficient to form a belief as to the truth of the remaining allegations in paragraph 66.

12 67. The allegations in paragraph 67 state conclusions of law to which no
13 response is required by BHCP. To the extent that a response is required, BHCP denies
14 the allegations in paragraph 67 to the extent that they relate to BHCP. The remaining
15 allegations in paragraph 67 are directed to other defendants, and therefore no response is
16 required by BHCP. To the extent that a response is required, BHCP denies, on
17 information and belief, that at any relevant time BHC manufactured, marketed or sold
18 any gadolinium-based contrast agents. BHCP is without knowledge or information
19 sufficient to form a belief as to the truth of the remaining allegations in paragraph 67.

20 68. BHCP denies the allegations in paragraph 68 to the extent that they relate to
21 BHCP. The remaining allegations in paragraph 68 are directed to other defendants, and
22 therefore no response is required by BHCP. To the extent that a response is required,
23 BHCP denies, on information and belief, that at any relevant time BHC manufactured,
24 marketed or sold any gadolinium-based contrast agents. BHCP is without knowledge or
25 information sufficient to form a belief as to the truth of the remaining allegations in
26 paragraph 68.

27 69. BHCP denies the allegations in paragraph 69 to the extent that they relate to
28 BHCP and/or to Magnevist®. The remaining allegations in paragraph 69 are directed to

1 other defendants, and therefore no response is required by BHCP. To the extent that a
2 response is required, BHCP denies, on information and belief, that at any relevant time
3 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
4 without knowledge or information sufficient to form a belief as to the truth of the
5 remaining allegations in paragraph 69.

6 **SIXTH CAUSE OF ACTION**

7 70. BHCP incorporates by reference its responses to the preceding paragraphs
8 as if fully set forth herein.

9 71. BHCP admits that it marketed Magnevist® in the United States as safe for
10 use with MRI when administered to patients by physicians in accordance with the
11 labeling and prescribing information approved by the FDA. BHCP further admits that it
12 provided appropriate warnings regarding the risks associated with the use of Magnevist®.
13 BHCP denies that it directly marketed Magnevist® to consumers. BHCP denies the
14 remaining allegations in paragraph 71 to the extent that they relate to BHCP and/or to
15 Magnevist®. The remaining allegations in paragraph 71 are directed to other defendants,
16 and therefore no response is required by BHCP. To the extent that a response is required,
17 BHCP denies, on information and belief, that at any relevant time BHC manufactured,
18 marketed or sold any gadolinium-based contrast agents. BHCP is without knowledge or
19 information sufficient to form a belief as to the truth of the remaining allegations in
20 paragraph 71.

21 72. BHCP denies the allegations in paragraph 72 to the extent that they relate to
22 BHCP and/or to Magnevist®. The remaining allegations in paragraph 72 are directed to
23 other defendants, and therefore no response is required by BHCP. To the extent that a
24 response is required, BHCP denies, on information and belief, that at any relevant time
25 BHC manufactured, marketed, sold, labeled or promoted any gadolinium-based contrast
26 agents. BHCP is without knowledge or information sufficient to form a belief as to the
27 truth of the remaining allegations in paragraph 72.

28 73. BHCP denies the allegations in paragraph 73 to the extent that they relate to

1 BHCP and/or to Magnevist®. The remaining allegations in paragraph 73 are directed to
2 other defendants, and therefore no response is required by BHCP. To the extent that a
3 response is required, BHCP denies, on information and belief, that at any relevant time
4 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
5 without knowledge or information sufficient to form a belief as to the truth of the
6 remaining allegations in paragraph 73.

7 74. BHCP admits that it marketed Magnevist® in the United States as safe for
8 use with MRI when administered to patients by physicians in accordance with the
9 labeling and prescribing information approved by the FDA. BHCP denies the remaining
10 allegations in paragraph 74 to the extent that they relate to BHCP and/or to Magnevist®.
11 The remaining allegations in paragraph 74 are directed to other defendants, and therefore
12 no response is required by BHCP. To the extent that a response is required, BHCP
13 denies, on information and belief, that at any relevant time BHC manufactured, marketed,
14 sold, labeled or promoted any gadolinium-based contrast agents. BHCP is without
15 knowledge or information sufficient to form a belief as to the truth of the remaining
16 allegations in paragraph 74.

17 75. BHCP denies the allegations in paragraph 75 to the extent that they relate to
18 BHCP and/or to Magnevist®. The remaining allegations in paragraph 75 are directed to
19 other defendants, and therefore no response is required by BHCP. To the extent that a
20 response is required, BHCP denies, on information and belief, that at any relevant time
21 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
22 without knowledge or information sufficient to form a belief as to the truth of the
23 remaining allegations in paragraph 75.

24 76. The allegations in paragraph 76 state conclusions of law to which no
25 response is required by BHCP. To the extent that a response is required, BHCP denies
26 the allegations in paragraph 76 to the extent that they relate to BHCP and/or to
27 Magnevist®. The remaining allegations in paragraph 76 are directed to other defendants,
28 and therefore no response is required by BHCP. To the extent that a response is required,

1 BHCP denies, on information and belief, that at any relevant time BHC manufactured,
2 marketed or sold any gadolinium-based contrast agents. BHCP is without knowledge or
3 information sufficient to form a belief as to the truth of the remaining allegations in
4 paragraph 76.

5 77. The allegations in paragraph 77 state conclusions of law to which no
6 response is required by BHCP. To the extent that a response is required, BHCP denies
7 the allegations in paragraph 77 to the extent that they relate to BHCP, except that BHCP
8 is without knowledge or information sufficient to form a belief as to the truth of the
9 allegations regarding what Plaintiff's healthcare providers relied upon. The remaining
10 allegations in paragraph 77 are directed to other defendants, and therefore no response is
11 required by BHCP. To the extent that a response is required, BHCP denies, on
12 information and belief, that at any relevant time BHC manufactured, marketed, sold,
13 labeled or promoted any gadolinium-based contrast agents. BHCP is without knowledge
14 or information sufficient to form a belief as to the truth of the remaining allegations in
15 paragraph 77.

16 78. BHCP denies the allegations in paragraph 78 to the extent that they relate to
17 BHCP and/or to Magnevist®. The remaining allegations in paragraph 78 are directed to
18 other defendants, and therefore no response is required by BHCP. To the extent that a
19 response is required, BHCP denies, on information and belief, that at any relevant time
20 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
21 without knowledge or information sufficient to form a belief as to the truth of the
22 remaining allegations in paragraph 78.

23 79. BHCP denies the allegations in paragraph 79 to the extent that they relate to
24 BHCP and/or to Magnevist®. The remaining allegations in paragraph 79 are directed to
25 other defendants, and therefore no response is required by BHCP. To the extent that a
26 response is required, BHCP denies, on information and belief, that at any relevant time
27 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
28 without knowledge or information sufficient to form a belief as to the truth of the

1 remaining allegations in paragraph 79.

2 80. BHCP denies the allegations in paragraph 80 to the extent that they relate to
3 BHCP and/or to Magnevist®. The remaining allegations in paragraph 80 are directed to
4 other defendants, and therefore no response is required by BHCP. To the extent that a
5 response is required, BHCP denies, on information and belief, that at any relevant time
6 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
7 without knowledge or information sufficient to form a belief as to the truth of the
8 remaining allegations in paragraph 80.

9 **SEVENTH CAUSE OF ACTION**

10 81. BHCP incorporates by reference its responses to the preceding paragraphs
11 as if fully set forth herein.

12 82. BHCP denies the allegations in paragraph 82 to the extent that they relate to
13 BHCP and/or to Magnevist®. The remaining allegations in paragraph 82 are directed to
14 other defendants, and therefore no response is required by BHCP. To the extent that a
15 response is required, BHCP denies, on information and belief, that at any relevant time
16 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
17 without knowledge or information sufficient to form a belief as to the truth of the
18 remaining allegations in paragraph 82.

19 83. BHCP denies the allegations in paragraph 83 to the extent that they relate to
20 BHCP and/or to Magnevist®. The remaining allegations in paragraph 83 are directed to
21 other defendants, and therefore no response is required by BHCP. To the extent that a
22 response is required, BHCP denies, on information and belief, that at any relevant time
23 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
24 without knowledge or information sufficient to form a belief as to the truth of the
25 remaining allegations in paragraph 83.

26 84. BHCP denies the allegations in paragraph 84 to the extent that they relate to
27 BHCP and/or to Magnevist®. The remaining allegations in paragraph 84 are directed to
28 other defendants, and therefore no response is required by BHCP. To the extent that a

1 response is required, BHCP denies, on information and belief, that at any relevant time
 2 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
 3 without knowledge or information sufficient to form a belief as to the truth of the
 4 remaining allegations in paragraph 84.

5 **EIGHTH CAUSE OF ACTION**

6 85. BHCP incorporates by reference its responses to the preceding paragraphs
 7 as if fully set forth herein.

8 86. The allegations in paragraph 86 state conclusions of law to which no
 9 response is required by BHCP. To the extent that a response is required, BHCP admits
 10 that it marketed Magnevist® in the United States as safe and effective for use with MRI
 11 when administered to patients by physicians in accordance with the labeling and
 12 prescribing information approved by the FDA. BHCP denies the remaining allegations
 13 in paragraph 86 to the extent that they relate to BHCP. The remaining allegations in
 14 paragraph 86 are directed to other defendants, and therefore no response is required by
 15 BHCP. To the extent that a response is required, BHCP denies, on information and
 16 belief, that at any relevant time BHC manufactured, marketed or sold any gadolinium-
 17 based contrast agents. BHCP is without knowledge or information sufficient to form a
 18 belief as to the truth of the remaining allegations in paragraph 86.

19 87. BHCP denies the allegations in paragraph 87 to the extent that they relate to
 20 BHCP and/or to Magnevist®. The remaining allegations in paragraph 87 are directed to
 21 other defendants, and therefore no response is required by BHCP. To the extent that a
 22 response is required, BHCP denies, on information and belief, that at any relevant time
 23 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
 24 without knowledge or information sufficient to form a belief as to the truth of the
 25 remaining allegations in paragraph 87.

26 88. BHCP denies the allegations in paragraph 88 to the extent that they relate to
 27 BHCP and/or to Magnevist®. The remaining allegations in paragraph 88 are directed to
 28 other defendants, and therefore no response is required by BHCP. To the extent that a

1 response is required, BHCP denies, on information and belief, that at any relevant time
2 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
3 without knowledge or information sufficient to form a belief as to the truth of the
4 remaining allegations in paragraph 88.

5 **NINTH CAUSE OF ACTION**

6 89. BHCP incorporates by reference its responses to the preceding paragraphs
7 as if fully set forth herein.

8 90. The allegations in paragraph 90 state conclusions of law to which no
9 response is required by BHCP. To the extent that a response is required, BHCP admits
10 that it marketed Magnevist® in the United States as safe and fit for use with MRI when
11 administered to patients by physicians in accordance with the labeling and prescribing
12 information approved by the FDA. BHCP denies the remaining allegations in paragraph
13 90 to the extent that they relate to BHCP. The remaining allegations in paragraph 90 are
14 directed to other defendants, and therefore no response is required by BHCP. To the
15 extent that a response is required, BHCP denies, on information and belief, that at any
16 relevant time BHC designed, manufactured, marketed, sold or distributed any
17 gadolinium-based contrast agents. BHCP is without knowledge or information sufficient
18 to form a belief as to the truth of the remaining allegations in paragraph 90.

19 91. BHCP denies the allegations in paragraph 91 to the extent that they relate to
20 BHCP and/or to Magnevist®. The remaining allegations in paragraph 91 are directed to
21 other defendants, and therefore no response is required by BHCP. To the extent that a
22 response is required, BHCP denies, on information and belief, that at any relevant time
23 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
24 without knowledge or information sufficient to form a belief as to the truth of the
25 remaining allegations in paragraph 91.

26 92. BHCP denies the allegations in paragraph 92 to the extent that they relate to
27 BHCP and/or to Magnevist®. The remaining allegations in paragraph 92 are directed to
28 other defendants, and therefore no response is required by BHCP. To the extent that a

1 response is required, BHCP denies, on information and belief, that at any relevant time
2 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
3 without knowledge or information sufficient to form a belief as to the truth of the
4 remaining allegations in paragraph 92.

5 93. BHCP denies the allegations in paragraph 93 to the extent that they relate to
6 BHCP and/or to Magnevist®. The remaining allegations in paragraph 93 are directed to
7 other defendants, and therefore no response is required by BHCP. To the extent that a
8 response is required, BHCP denies, on information and belief, that at any relevant time
9 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is
10 without knowledge or information sufficient to form a belief as to the truth of the
11 remaining allegations in paragraph 93.

12 **TENTH CAUSE OF ACTION**

13 94. BHCP incorporates by reference its responses to the preceding paragraphs
14 as if fully set forth herein.

15 95. The allegations in paragraph 95 state conclusions of law to which no
16 response is required by BHCP. To the extent that a response is required, BHCP denies
17 the allegations in paragraph 95, including subparagraphs a. through g., to the extent that
18 they relate to BHCP and/or to Magnevist®. The remaining allegations in paragraph 95
19 are directed to other defendants, and therefore no response is required by BHCP. To the
20 extent that a response is required, BHCP denies, on information and belief, that at any
21 relevant time BHC manufactured, marketed or sold any gadolinium-based contrast
22 agents. BHCP is without knowledge or information sufficient to form a belief as to the
23 truth of the remaining allegations in paragraph 95.

24 96. BHCP denies the allegations in paragraph 96 to the extent that they relate to
25 BHCP and/or to Magnevist®. The remaining allegations in paragraph 96 are directed to
26 other defendants, and therefore no response is required by BHCP. To the extent that a
27 response is required, BHCP denies, on information and belief, that at any relevant time
28 BHC manufactured, marketed or sold any gadolinium-based contrast agents. BHCP is

1 without knowledge or information sufficient to form a belief as to the truth of the
2 remaining allegations in paragraph 96.

3 **ELEVENTH CAUSE OF ACTION**

4 97. BHCP incorporates by reference its responses to the preceding paragraphs
5 as if fully set forth herein.

6 98. BHCP is without knowledge or information sufficient to form a belief as to
7 the truth of the allegations in paragraph 98.

8 99. BHCP denies the allegations in paragraph 99 to the extent that they relate to
9 BHCP. The remaining allegations in paragraph 99 are directed to other defendants, and
10 therefore no response is required by BHCP. To the extent that a response is required,
11 BHCP denies, on information and belief, that at any relevant time BHC manufactured,
12 marketed or sold any gadolinium-based contrast agents. BHCP is without knowledge or
13 information sufficient to form a belief as to the truth of the remaining allegations in
14 paragraph 99.

15 100. BHCP denies that Plaintiffs are entitled to any relief this action, including
16 but not limited to the specific items of relief requested by Plaintiffs in the Complaint.

17 101. BHCP denies each and every allegation in the Complaint that relates to or
18 is directed to BHCP unless such allegations are expressly admitted in this Answer.

19 **DEFENSES**

20 Discovery and investigation may reveal that one or more of the following defenses
21 should be available to BHCP in this matter. BHCP accordingly preserves the right to
22 assert these separate and additional defenses. Upon completion of discovery, if the facts
23 warrant, BHCP may withdraw any of these additional defenses as may be appropriate.
24 BHCP further reserves the right to amend its Answer and defenses, and to assert
25 additional defenses and other claims, as discovery proceeds.

26 In setting forth the following separate and additional defenses, BHCP does not
27 concede that it bears the burden of proof or persuasion as to any of them.

FIRST DEFENSE

Plaintiffs' Complaint, and each and every count contained therein, fails to state a cause of action or claim upon which relief can be granted against BHCP.

SECOND DEFENSE

Some or all of Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or statutes of repose.

THIRD DEFENSE

Plaintiffs' claims against BHCP are barred, in whole or in part, by laches, waiver and/or estoppel.

FOURTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate Plaintiffs' alleged damages.

FIFTH DEFENSE

The acts and omissions of Plaintiffs caused and/or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrines of contributory negligence and/or comparative negligence. Plaintiffs' recovery, if any, therefore is barred or should be apportioned in accordance with applicable law.

SIXTH DEFENSE

The alleged injuries sustained by Plaintiffs, if any, were caused, in whole or in part, by pre-existing physical, medical, and/or physiological conditions, for which BHCP has no legal responsibility.

SEVENTH DEFENSE

If Plaintiffs suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiffs. Plaintiffs' recovery accordingly is barred or should be reduced by Plaintiffs' assumption of the risk.

EIGHTH DEFENSE

The injuries and damages claimed by Plaintiffs, if any, resulted from an

1 intervening or superseding cause and/or causes, and any act or omission on the part of
 2 BHCP was not the proximate and/or competent producing cause of such alleged injuries
 3 and damages.

4 **NINTH DEFENSE**

5 The injuries and damages claimed by Plaintiffs, if any, are barred or must be
 6 reduced because those damages arose from the acts or omissions of persons or entities
 7 other than BHCP.

8 **TENTH DEFENSE**

9 If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is
 10 expressly denied, said injuries or expenses were caused by the unforeseeable alteration,
 11 improper handling, or other unforeseeable misuse of the prescription drug Magnevist®.
 12 Plaintiffs' recovery is accordingly barred.

13 **ELEVENTH DEFENSE**

14 The alleged injuries and damages, if any, were the result of unavoidable
 15 circumstances that could not have been prevented by any person, including BHCP.

16 **TWELFTH DEFENSE**

17 The claims in the Complaint against BHCP are barred in whole or in part by the
 18 learned intermediary doctrine. Magnevist® is a prescription pharmaceutical which was
 19 available only upon the prescription of a licensed physician and is indicated for use by
 20 physicians for only certain purposes. Any warnings that BHCP gave were transmitted to
 21 prescribing physicians and/or healthcare providers. Under applicable law, the only
 22 obligation of BHCP is to warn the prescribing physician and/or healthcare providers, and
 23 that obligation was fulfilled.

24 **THIRTEENTH DEFENSE**

25 Plaintiffs' Complaint fails to state a claim upon which relief can be granted against
 26 BHCP in that the methods, standards, and techniques utilized with respect to the design,
 27 manufacture, marketing and sale of Magnevist®, including but not limited to adequate
 28 warnings and instructions with respect to the product's use included in the product's

1 package insert and other literature, conformed to the applicable state of the art. The
2 product in question, including its labeling approved by the FDA, complied with the state
3 of scientific and medical knowledge available to BHCP at the time of its design, testing,
4 manufacture, distribution, marketing and sale. Plaintiffs' recovery accordingly is barred.

5 **FOURTEENTH DEFENSE**

6 Plaintiffs' claims are barred because Magnevist® was neither defective nor
7 unreasonably dangerous in its design, manufacture or marketing and was reasonably safe
8 and reasonably fit for its intended use, thereby barring Plaintiffs' recovery. The warnings
9 and instructions accompanying Magnevist® at the time of the occurrence or injuries
10 alleged by Plaintiffs were legally adequate warnings and instructions.

11 **FIFTEENTH DEFENSE**

12 Plaintiffs' claims are barred as a matter of law pursuant to Restatement (Second)
13 of Torts § 402A, comment k.

14 **SIXTEENTH DEFENSE**

15 The prescription drug Magnevist® complied with the applicable product safety
16 regulations promulgated by the FDA. Compliance with such regulations demonstrates
17 that due care was exercised with respect to the design, manufacture, testing, marketing
18 and sale of this prescription drug, and that it was neither defective nor unreasonably
19 dangerous. Plaintiffs' recovery is accordingly barred.

20 **SEVENTEENTH DEFENSE**

21 Any claims by Plaintiffs relating to alleged communications with regulatory
22 agencies of the United States government are barred in whole or in part by operation of
23 applicable law, including First and Fourteenth Amendment rights to petition the
24 government.

25 **EIGHTEENTH DEFENSE**

26 Plaintiffs' claims are barred in whole or in part because the commercial speech
27 relating to Magnevist® was not false or misleading and is protected under the First
28 Amendment of the United States Constitution and the applicable state constitution.

NINETEENTH DEFENSE

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

TWENTIETH DEFENSE

Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal regulation of prescription drug manufacturing, testing, marketing, and labeling.

TWENTY-FIRST DEFENSE

Plaintiffs' claims are preempted, in whole or in part, by reason of the FDA's preamble to the *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922 (Jan. 24, 2006).

TWENTY-SECOND DEFENSE

Plaintiffs cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiffs is subject to the exclusive regulation of the FDA.

TWENTY-THIRD DEFENSE

This Court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

TWENTY-FOURTH DEFENSE

Plaintiffs did not detrimentally rely on any labeling, warnings or information concerning Magnevist®.

TWENTY-FIFTH DEFENSE

Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

TWENTY-SIXTH DEFENSE

To the extent that Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

TWENTY-SEVENTH DEFENSE

To the extent that Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of BHCP, if any, should be reduced accordingly.

TWENTY-EIGHTH DEFENSE

Plaintiffs' Complaint fails to state a claim against BHCP upon which relief can be granted as to costs, attorneys' fees, expenses, pre-judgment interest, post-judgment interest or estoppel.

TWENTY-NINTH DEFENSE

Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

THIRTIETH DEFENSE

Plaintiffs' Complaint fails to state a claim against BHCP upon which relief can be granted for several or joint and several liability.

THIRTY-FIRST DEFENSE

Plaintiffs' claims for breach of warranty are barred because Plaintiffs failed to give timely notice of any alleged breach of warranty.

THIRTY-SECOND DEFENSE

BHCP did not sell or distribute Magnevist® directly to Plaintiffs, and Plaintiffs did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiffs' claims for breach of warranty are barred by lack of privity between Plaintiffs and BHCP.

THIRTY-THIRD DEFENSE

Plaintiffs' claims for breach of warranty, express or implied, are barred by the

1 applicable state's Uniform Commercial Code or other applicable law.

2 **THIRTY-FOURTH DEFENSE**

3 Plaintiffs' Complaint fails to state a claim for fraud, statutory fraud,
4 misrepresentation, omission, suppression and/or concealment, and fails to allege the
5 circumstances constituting fraud with the particularity required by the Federal Rules of
6 Civil Procedure.

7 **THIRTY-FIFTH DEFENSE**

8 Plaintiffs' Complaint fails to state a claim against BHCP upon which relief can be
9 granted for punitive or exemplary damages.

10 **THIRTY-SIXTH DEFENSE**

11 BHCP denies any conduct for which punitive or exemplary damages could or
12 should be awarded and denies that Plaintiffs have produced evidence sufficient to support
13 or sustain the imposition of punitive damages against BHCP pursuant to the applicable
14 standard(s) of proof.

15 **THIRTY-SEVENTH DEFENSE**

16 Permitting recovery of punitive or exemplary damages in this case would be
17 unconstitutionally vague and/or overbroad and would violate BHCP's constitutional
18 rights as secured by the Fifth and Seventh Amendments to the United States Constitution,
19 would violate its rights to due process and equal protection under the Fourteenth
20 Amendment of the United States Constitution and the prohibition against excessive fines
21 in the United States Constitution, and would contravene other provisions of the United
22 States, California and Arizona Constitutions and any other applicable state Constitutions.

23 **THIRTY-EIGHTH DEFENSE**

24 Plaintiffs cannot recover punitive or exemplary damages against BHCP because
25 such an award, which is penal in nature, would violate BHCP's constitutional rights
26 under the United States Constitution and any other applicable state constitution, unless
27 BHCP is afforded the same procedural safeguards as are criminal defendants, including
28 but not limited to the right to avoid self incrimination, the right to forego production and

1 disclosure of incriminating documents and the right to the requirement of a level of proof
2 beyond a reasonable doubt.

3 **THIRTY-NINTH DEFENSE**

4 Any imposition of punitive or exemplary damages in this case against BHCP
5 would contravene the Commerce Clause of the United States Constitution, in that such an
6 award would constitute, if imposed, an undue and unreasonable burden on interstate
7 commerce.

8 **FORTIETH DEFENSE**

9 With respect to Plaintiffs' demand for punitive or exemplary damages, BHCP
10 specifically incorporates by reference any and all standards or limitations regarding the
11 determination and enforceability of punitive or exemplary damages awards under
12 applicable state law.

13 **FORTY-FIRST DEFENSE**

14 Any award of punitive or exemplary damages against BHCP is barred to the extent
15 that it is inconsistent with the standards and limitations set forth in *BMW of North*
16 *America, Inc. v. Gore*, 517 U.S. 559, 134 L. Ed. 2d 809, 116 S. Ct. 1589 (1996), *State*
17 *Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003) and *Philip*
18 *Morris USA v. Williams*, 127 S. Ct. 1057 (2007).

19 **FORTY-SECOND DEFENSE**

20 No act or omission of BHCP was vile, base, willful, malicious, wanton, oppressive
21 or fraudulent, or done with a conscious disregard for the health, safety, and rights of
22 Plaintiffs and others, or for the primary purpose of increasing profits. Nor was any act or
23 omission of BHCP done with actual malice, fraud or oppression as defined in California
24 Civil Code section 3294, or with actual malicious or gross negligence that evidences a
25 willful, wanton, or reckless disregard for the safety of others, or an evil mind, and BHCP
26 did not commit actual fraud. Therefore, Plaintiffs' Complaint fails to state a claim upon
27 which relief can be granted for punitive or exemplary damages. Plaintiffs' Complaint
28 seeks damages in excess of those permitted by law. BHCP asserts any statutory or

1 judicial protection from punitive or exemplary damages that is available under the
2 applicable law, and any award of punitive or exemplary damages is barred.

3 **FORTY-THIRD DEFENSE**

4 Plaintiffs' Complaint fails to state a claim for unlawful conduct under the Arizona
5 consumer protection statute because BHCP completely complied with the applicable law
6 in connection with the marketing and sale of Magnevist®.

7 **FORTY-FOURTH DEFENSE**

8 Plaintiffs' Complaint fails to state a claim for misleading or unfair advertising or
9 for deceptive business practices under the Arizona consumer protection statute because
10 BHCP's labeling and advertising for Magnevist® was not misleading, unfair or
11 deceptive.

12 **FORTY-FIFTH DEFENSE**

13 Plaintiffs' claims are barred in whole or in part because the Arizona consumer
14 protection statute is insufficiently definite to provide adequate or fair notice of the
15 conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth
16 Amendments to the United States Constitution and the due process protections of the
17 applicable state constitution.

18 **FORTY-SIXTH DEFENSE**

19 Plaintiffs' claims are barred in whole or in part because Arizona consumer
20 protection statute unconstitutionally burdens interstate business practices relating to
21 prescription drugs, which are heavily regulated by the FDA.

22 **FORTY-SEVENTH DEFENSE**

23 Venue is improper.

24 **FORTY-EIGHTH DEFENSE**

25 This Court is not the proper forum and is not a convenient forum for the just
26 adjudication of Plaintiffs' claims.

27 **FORTY-NINTH DEFENSE**

28 The injuries claimed by Plaintiffs, if any, were the result of an idiosyncratic

1 reaction to the product.

2 **FIFTEENTH DEFENSE**

3 Upon information and belief, Plaintiffs consented to the alleged wrongful conduct
4 at issue, which bars Plaintiffs' claims in whole or in part.

5 **FIFTY-FIRST DEFENSE**

6 To the extent that California law is applicable to Plaintiffs' claims, Plaintiffs' non-
7 economic loss must be allocated in accordance with the provision of California Civil
8 Code Section 1431.1 ("Proposition 51").

9 **FIFTY-SECOND DEFENSE**

10 To the extent that Arizona law is applicable to Plaintiffs' claims, Plaintiffs'
11 Complaint fails to state a claim upon which relief can be granted for several or joint and
12 several liability and any recovery should be apportioned pursuant to the Uniform
13 Contribution Among Tortfeasors Act, A.R.S. § 12-2501, *et seq.*

14 **FIFTY-THIRD DEFENSE**

15 Any recovery by Plaintiffs is barred or should be reduced pursuant to A.R.S. § 12-
16 2505 and/or common law and applicable statutes because of the contributory negligence,
17 contributory fault, failure to mitigate damages and/or assumption of the risk by Plaintiffs.

18 **FIFTY-FOURTH DEFENSE**

19 Pursuant to A.R.S. § 12-2506(B), BHCP alleges that a person or entity not a party
20 to this action was wholly or partially at fault in causing the alleged injuries and/or
21 damages for which Plaintiffs seek recovery.

22 **FIFTY-FIFTH DEFENSE**

23 BHCP denies making any express or implied warranties to Plaintiffs. In the
24 alternative, BHCP alleges that any and all warranties that may form a basis for Plaintiffs'
25 claims were adequately disclaimed. In the alternative, Plaintiffs failed to give timely
26 notice of the breach of warranty claims, as required by Arizona law and specifically,
27 A.R.S. § 44-1521, *et seq.*, and Plaintiffs' claims are therefore barred.

1 **FIFTY-SIXTH DEFENSE**

2 Plaintiffs' claims are barred as a matter of law by A.R.S. § 12-683.

3 **FIFTY-SEVENTH DEFENSE**

4 Plaintiffs' claims for punitive damages are barred by A.R.S. § 12-701(A).

5 **FIFTY-EIGHTH DEFENSE**

6 Under no circumstances may BHCP be held derivatively liable for an award of
7 punitive damages.

8 **FIFTY-NINTH DEFENSE**

9 BHCP adopts and incorporates by reference all defenses pleaded by other
10 defendants except to the extent that they are inconsistent with BHCP's defenses pleaded
11 in this Answer.

12 WHEREFORE, BHCP requests that Plaintiffs' Complaint be dismissed
13 with prejudice, that judgment be entered in favor of BHCP and against Plaintiffs, and that
14 BHCP be awarded the costs of this action, together with such other and further relief as
15 may be appropriate.

16 **JURY DEMAND**

17 BHCP hereby demands a trial by jury on all issues so triable.

18
19 Dated: March 11, 2008

DRINKER BIDDLE & REATH LLP

20
21 /S/ Rodney M. Hudson

RODNEY M. HUDSON

22 Attorneys for Defendant
23 BAYER HEALTHCARE
24 PHARMACEUTICALS INC.
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